REMARKS

In the last Office Action, claims 10 and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over US 6,203,525 to Whayne et al. ("Whayne") in view of US 4,619,643 to Bai, and claims 12-15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Whayne in view of Bai and further in view of US 5,542,938 to Avellanet et al. ("Avellanet"). Claims 16-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Whayne in view of Avellanet. Claims 22-29 were withdrawn from further consideration as being drawn to a non-elected invention.

Applicant respectfully requests reconsideration and withdrawal of the prior art rejections and the restriction requirement.

Traversal of Rejection of Claims 10-15

Independent claim 10 has been rejected as unpatentable over Whayne in view of Bai. Applicant respectfully traverses this rejection and submits that independent claim 10 patentably distinguishes over Whayne in combination with Bai.

Whayne discloses a catheter assembly having concentric, relatively movable inner and outer bodies 28 and 36. A spline 26 (Fig. 2A) or a tapered wire 30 (Fig. 2B) is provided to adjust the stiffness of the inner body 28. A multiple electrode structure 20 having electrode elements 22 is attached to the distal end of the inner body 28 to sense electrical events in

heart tissue or to transmit electrical pulses to measure the impedance of heart tissue and the like (column 5, lines 50-59). If it is desired to prevent relative rotation between the inner and outer bodies 28 and 36 to maintain the electrode elements 22 in a fixed orientation, the bodies may have an elliptically keyed arrangement (Fig. 8A). If it is desired to permit a small range of relative rotation between the inner and outer bodies 28' and 36', the interior of the outer body 36' is shaped to permit limited rotation of the inner body 28' (Fig. 8B). See column 10, lines 11-29.

Independent claim 10 recites a control device that enables and impedes relative movement between the envelope body and the inner body to respectively impart flexibility and rigidity to the entire device in a controllable manner. The Examiner contends that Whayne discloses a control device 20 that corresponds to the claimed control device. Applicant respectfully disagrees. In Whayne, reference numeral 20 denotes the multiple electrode structure comprised of electrode elements 22 which, as noted above, function to sense electrical events in heart tissue or to transmit electrical pulses to measure the impedance of heart tissue and the like -- not to controllably impart flexibility and rigidity to the entire device. Instead, in Whayne, the flexibility and rigidity of the entire device is controlled by either the spline 26 (Fig. 2A) or the tapered wire (Fig. 2B).

Claim 10 further recites that the envelope body and the inner body each have a polygonal cross section such that the envelope body and the inner body can be rotated relative to one another by the control device in such a way that the inner body makes contact at least partially with the envelope body. No similar structure is disclosed by Whayne. In the Fig. 8A embodiment of Whayne, the inner body 28 cannot rotate relative to the outer body 36. As stated in the reference, "[t]he interference (elliptically keyed) arrangement in Fig. 8A prevents rotation of the structure 20 and also provides improved torque response and maintains the electrode segments 22 in a fixed orientation with respect to the sheath 36." In the Fig. 8B embodiment of Whayne, the envelope body 36' and the inner body 28' can rotate relative to one another a limited extent by manual manipulation by a physician -- not by a control device as required by claim 10.

As recognized by the Examiner, the inner and outer bodies 28',36' of Whayne do not have polygonal cross sections, as required by claim 10. To supply this deficiency, the Examiner contends that Bai discloses a double lumen catheter in which the inner and outer bodies have a polygonal cross section as shown in Figs. 3c-3e and that it would have been obvious to one of ordinary skill in the art to modify the Whayne device so that the envelope body 36' and the inner body 28' have a polygonal cross section for the purpose of making the outer envelope body as

small as possible while still imparting structural rigidity so as to make insertion easy but prevent the chance of buckling. Applicant vigorously disagrees.

In Bai, Figs. 3c-3e illustrate altlernative venous lumens at the distal end part of different catheter embodiments. More particularly, Bai discloses various embodiments of a double lumen catheter of the type shown in Fig. 1, in which the catheter has an arterial lumen 16 and a venous lumen 18 along an intermediate part 17 of the catheter. To facilitate insertion of the catheter into a blood vessel, an obturator 31 is inserted into and extends along the length of the venous lumen 18, and a guidewire 41 extends through the obturator 31, as illustrated in the embodiments of Figs. 3c-3e. Another obturator 32 is inserted into and extends along the length of the arterial lumen 16 as illustrated in the different embodiments of Figs. 1 and 2. The obturator 31 is of solid construction except for the opening through which the guidewire 41 extends, and the obturator 32 is of solid construction. The obturator 31 has the same cross-sectional shape as the lumen 18, and the obturator 32 has the same cross-sectional shape as the lumen 16 (column 7, lines 10-19) so that after the two obturators and the guidewire are assembled within the lumens, "there is preferably substantially no empty space in the catheter body A throughout its length and the body A cannot be squashed by pinching or kneading between the thumb and index finger" (column 7, lines 29-33). Consequently,

in Bai, the obturators 31 and 32 are rotationally rigid with respect to the catheter body A for the purpose of preventing rotational twisting of the obturators and facilitating their insertion into the lumens.

One of ordinary skill in the art would readily recognize that the obturator/catheter body structures illustrated in Figs. 3c-3e would not be applicable to the Fig. 8B embodiment of Wayne since the former prevent rotation of the obturator (inner body) 31 relative to the catheter body (outer body) 15. Thus, contrary to the Examiner's contention, one skilled in the art would not have found it obvious to modify the Whayne device in view of Bai to form the outer envelope body 36' and the inner body 28' with polygonal cross sections as to do so would preclude limited rotational movement of the inner body relative to the outer envelope body. In point of fact, the embodiments illustrated in Figs. 3c-3e of Bai are similar to the Fig. 8A embodiment of Whayne in which the inner and outer bodies have the same cross-sectional shape to prevent relative rotation between the two bodies, which is contrary to the claimed invention.

Dependent claim 11 recites that the envelope body and the inner body each have a hexagonal cross section and are dimensioned in such a way that the inner body, with the two bodies in their mutually rotated state, makes contact at all of its corners with an inner wall of the envelope body. This feature is not taught by Bai since in the reference, the inner

body (obturator) cannot rotate relative to the outer body (catheter body) and thus the two bodies do not have a mutually rotated state in which the inner body makes contact at all of its corners with an inner wall of the outer body. Base claim 10 requires that the outer and inner bodies can be rotated relative to one another, and claim 11 requires that when the two bodies are in their mutually rotated state, the inner body makes contact at all of its corners with an inner wall of the outer body. This limitation is not found in either Whayne or Bai.

Furthermore, claim 11 requires that the envelope body and the inner body each have a hexagonal cross section. In addressing this limitation, the Examiner acknowledges that Whayne and Bai disclose a cross section with three sides but not six sides and contends that it would have been obvious to one skilled in the art that six sides could be used instead of three, citing Gardner v. TEC Systems, Inc. However, in the cited case, the Federal Circuit held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. In the present case, the difference between the claimed invention and the prior art is not one of relative dimensions but one of different structures. According to the Examiner, the advantages of six sides over three sides is to

impart structural rigidity, ease insertion of the device and allow the shape of the outer configuration to adapt to different geometries within a body region, all of which are due to the structural difference of six sides versus three sides. One skilled in the art would not have been motivated by any teaching in Whayne or Bai to provide the outer and inner bodies with hexagonal cross sections.

Dependent claims 12-15 are each separately patentable. Whayne relates to multiple electrode structures in the context of catheter-based cardiac ablation in which electrical wires extend through a lumen in a catheter tube to electrode elements 22 to conduct ablating energy to the electrode elements. One skilled in the art would not have been led by any teaching in Avellanet to modify the Whayne device to apply positive or negative pressure to the space between the outer and inner bodies, or form the outer and inner bodies of magnetizeable material or provide them with a magnetizeable coating, as required by claims 12-15. Avellanet relates to balloon catheters which require an inflation fluid to inflate the balloon, and such technology is inapplicable to Whayne which relates to a multiple electrode structure for a catheter to sense electrical events in heart tissue or to transmit electrical energy to ablate heart tissue. Thus claims 12-15 patentably distinguish over Whayne in combination with Bai and Avellanet.

Traversal of Rejection of Claims 16-21

Independent claim 16 has been rejected as being unpatentable over Whayne in view of Avellanet, the Examiner contending that it would have been obvious to one of ordinary skill in the art to modify the Whayne device to include a magnetic coating on the outer envelope body, as suggested and taught by Avellanet, for the purpose of being able to have better control of the catheter when it is positioned in the body. Applicant respectfully traverses this rejection and submits that independent claim 16 patentably distinguishes over Whayne in combination with Avellanet.

Avellanet relates to an apparatus for facilitating an exchange of catheters during a surgical procedure. As shown in Fig. 1, a guiding catheter 10 guides a guidewire 12, and the guidewire extends through a holding attachment 20 at the proximal end of the catheter 10. The guidewire 12 is provided with a magnetic section M in the region where the guidewire passes through the holding attachment 20, and the holding attachment 20 houses a magnet 22 which is magnetically coupled to the magnetic section M of the guidewire 12. During a surgical procedure, if a physician wishes to exchange the balloon catheter 14, the physician pulls on the proximal end 14a of the balloon catheter 14 while holding the holding attachment 20. The magnetic coupling between the magnet 22 and the magnetic section M of the guidewire 12 retains the guidewire in position while the balloon

catheter 14 is withdrawn and replaced by another. The magnetic guidewire section M is preferably four inches and the magnet 22 has a length dimension of approximately one or two inches (column 6, lines 50-54).

The holding attachment 20 is positioned at the proximal end of the guiding catheter 10 and does not generate magnetic fields of different polarity along the lengths of the guiding catheter 10 and the balloon catheter 14 for the selective production of a mutual attraction of the two bodies, as specified in claim 16. Thus even if it would have been obvious to modify Whayne in view of Avellanet, the modified Whayne device would have a magnet disposed only at the proximal end of the catheter assembly, and the magnet would not be located anywhere near the vicinity of the inner and outer bodies 28 and 36 at the distal end of the catheter assembly. Thus the modified Whayne device would not resemble the claimed invention.

Moreover, in none of the embodiments disclosed by Avellanet are magnet fields of different polarity generated along the length of outer and inner bodies for the selective production of a mutual attraction of the two bodies that enables and impedes relative movement between the outer and inner bodies to respectively impart flexibility and rigidity to the entire device, as recited in claim 16. In Avellanet, the attraction between the magnetic section M of the guidewire 12 and the magnet 22 of the holding attachment 20 does not enable or impede

relative movement between the guiding catheter 10 and the balloon catheter 14. By contrast, in the reference, the magnet 22 magnetically attracts the magnetic section M of the guidewire 12 to retain the guidewire in place while the balloon catheter 14 is withdrawn. Thus Whayne in combination with Avellanet does not disclose or suggest the claimed invention.

Dependent claims 17-21 each are separately patentable over Whayne in combination with Avellanet for the reasons discussed above in connection with claims 12-15.

Traversal of Restriction Requirement

The Examiner maintained the restriction requirement between claims 10-21 of Group I and claims 22-29 of Group II but based the restriction on new grounds, namely, that Group I requires a control device and specifies that the material of the device must be flexible and torsionally resistant. Applicant respectfully traverses the restriction requirement and requests withdrawal, or at least partial withdrawal, thereof.

Independent claim 22 of Group II recites inner and outer bodies having polygonal cross sections and being movable relative to one another to impart flexibility to the device and being selectively rotationally movable relative to one another to a limited extent to bring the inner and outer bodies into contact with one another to impart stiffness to the device. In order that the inner and outer bodies impart flexibility or stiffness

to the device requires that the bodies be formed of flexible and torsionally resistant material so that this feature is inherently present in the claim.

Claim 25, which ultimately depends on claim 22, specifies that the device includes a control device that controls relative rotational movement of the inner and outer bodies. Thus claim 25 when read in conjunction with base claim 22 relates to the same invention as the claims of Group I. Stated otherwise, the claims of Group I and Group II relate to a single general inventive concept, thereby precluding restriction.

Independent claim 26, like independent claim 22, inherently requires that the inner and outer bodies be formed of flexible and torsionally resistant material though does not recite a control device. Instead, this claim recites in means-plus-function format the structure for creating magnetic attraction forces between the inner and outer bodies, which is akin to the control device.

Applicant, therefore, respectfully requests reconsideration and withdrawal of the restriction requirement and an action on the merits of claims 22-29.

In view of the foregoing, favorable reconsideration and allowance of claims 10-21 together with examination on the merits of claims 22-29 are respectfully requested.

Respectfully submitted,

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APRIL 12, 2010
Date